K123425

FEB 2 0 2013

Smith & Nephew, Inc. TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL
Traditional Premarket Notification

510(k) Summary

Date Prepared: February 1, 2013

Submitter Information	Contact Information
Smith & Nephew, Inc., Endoscopy Division 150 Minuteman Road Andover, MA 01810	Catherine Kilshaw Senior Regulatory Affairs Specialist Phone: (508) 337-4104 Fax: (978) 749-1443

Device Name (Unmodified)	
Trade or proprietary name	TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 and Needles, SL
Common or usual name	Soft Tissue Fixation Device (MBI)
Classification name	21 CFR 888.3040 Fastener, fixation, nondegradable, soft tissue (Class II)

Legally Marketed Predicate Device

The Smith & Nephew TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K053344 **Bioraptor Suture Anchor, TWINFIX Ti 2.8mm & TWINFIX 3.5mm**
(Cleared February 23, 2006)

K972326 **PEBA Anchor/Suture Combination**
(Cleared February 6, 1998)

Device Description

The Smith & Nephew TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL are designed to provide secure reattachment of soft tissue to bone. Attachment of soft tissue is performed by the surgeon's preferred technique. TWINFIX Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL consists of a titanium alloy suture anchor and non-absorbable sutures with attached stainless steel needles. The non-absorbable sutures are offered either braided, silicone or PTFE impregnated, polyester (USP) or braided, uncoated, UHMW polyethylene and UHMW polyethylene with monofilament polypropylene or nylon co-braid. An insertion device is also offered which contains a stainless steel shaft with a ABS and polycarbonate handle. The TWINFIX Ti is designed to provide secure reattachment of soft tissue to bone. Attachment of soft tissue is performed by the surgeon's preferred technique.

Indications for Use

Smith & Nephew TWINFIX® Ti Preloaded Suture Anchor with Needles, SL are intended for use only for the fixation of non-absorbable, synthetic, surgical suture material for the following indications.

Shoulder

Bankart lesion repairs, SLAP lesion repairs, Acromiolavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsulolabral reconstructions, Biceps tenodesis, and Deltoid Repairs

Foot and Ankle

Hallux valgus reconstruction, Medial or Lateral instability repairs/reconstructions, Achilles tendon repair/reconstructions, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstructions

Elbow, Wrist and Hand

Scapholunate ligament reconstruction, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, Biceps tendon reattachment

Knee

Extra-capsular repairs: Medial collateral ligament repair, Lateral collateral ligament repair, Posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair – Vastus medialis obliquous advancement

Technological Characteristics

The Smith & Nephew TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL is substantially equivalent in design and fundamental scientific technology to the defined predicate devices and raise no new issues of safety and efficacy.

Performance Data

Mechanical test data demonstrates the device has met the performance specifications for insertion and pull out strength and therefore, is considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2013

Smith & Nephew, Inc., Endoscopy Division
% Ms. Catherine Kilshaw
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K123425
Trade/Device Name: TWINFIX™ Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 6, 2012
Received: November 26, 2012

Dear Ms. Kilshaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123425

Device Name: TWINFIX® Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 with Needles, SL

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Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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